### **REMARKS**

No new matter has been added by the amended language in claims 14 and 15. The amended language relates to clarification of these claims in connection with part of the rejection under 35 U.S.C. §112, second paragraph. Support is at line 17 of page 7. Thus, the Examiner is respectfully requested to enter the amended language.

# Rejections under 35 U.S.C. §112, second paragraph:

In the Official Action, Examiner Yu rejected all of pending claims 1-15 under 35 U.S.C. §112, second paragraph, as being indefinite.

Claim 1 is independent, and each of dependent claims 2-15 depends back to independent claim 1.

More specifically, the Examiner alleged that the terms "gently" and gentle" in independent claim 1 and dependent claim 7, respectively, [with regard to gliding the solid block] are relative terms and not defined by the claim and that the specification does not provide a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant respectfully traverses, and points out that independent claim 1 in clause (B) specifically states:

in a manner insufficient to cause abrasion

and debridement of the affected skin

vis-à-vis gently gliding the solid block, and thus, independent claim 1 clearly defines what is meant by gently. Additionally, lines 27 - 28 of page 4 of applicant's specification and line 5 of page 10 of applicant's specification both also state:

in a manner insufficient to cause abrasion

and debridement of the affected skin

vis-à-vis gently gliding the solid block. Hence, applicant's specification clearly provides a standard for ascertaining the requisite degree, and one of ordinary skill in the art clearly would be reasonably apprised of the scope of the invention.

Accordingly, applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §112, second paragraph, with respect to the term "gently" in independent claim 1 and the term "gentle" in dependent claim 7, and thus, withdraw the rejection with respect to all of claims 1 - 15.

Next, the Examiner alleged that the term "other topical medicaments and cosmetics for the topical treatment of cellulite" in dependent claim 6 renders the claim vague and indefinite, as the metes and bounds of the scope of the limitation is unclear.

Applicant respectfully points out that dependent claim 6 is clear on its face that, in accordance with an embodiment of the invention as claimed in this claim, the block of salt is <u>free</u> of other topical medicaments and cosmetics for the topical treatment of cellulite.

The metes and bounds are clearly ascertainable, namely that other cellulite topical medicaments and cosmetics are not present in the block, in addition to a salt selected from sodium chloride and/or potassium chloride. There is no requirement in patent law to list ad infinitum every possible cellulite topical medicament and cosmetic that is not present.

Also, support for dependent claim 6 can be found in the paragraph at lines 18 and 19 of page 8 of applicant's specification. This paragraph specifically states:

Even more preferably, the block of NaCl and/or KCl also should be free of any other medicaments or cosmetics for the topical treatment of cellulite.

Thus, applicant's specification provides a standard to one of ordinary skill in the art for being apprised of the metes and bounds of the scope.

Accordingly, applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §112, second paragraph, of dependent claim 6 with respect to the term "other topical medicaments and cosmetics for the topical treatment of cellulite".

Then, the Examiner alleged that the term "naturally present" in dependent claim 14 renders the claim vague and indefinite, as it is not clear whether the ingredients must be naturally derived.

The ingredients do not have to be naturally derived. Applicant has clarified this by the above-noted amended language "of the kind" inserted into claim 14, and also into claim 15 which depends on claim 14.

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Accordingly, applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §112, second paragraph, of dependent claim 14 with respect to the term "naturally present".

Lastly, the Examiner alleged that the terms "potassium protein complexes" and "sodium protein complexes" render dependent claim 15 vague and indefinite, and there is no disclosure in applicant's application for a skilled artisan to determine the metes and bounds of the scope of the claim.

Applicant respectfully points out that the "potassium protein complexes" and "sodium protein complexes" are of the kind of naturally present in human extracellular fluid and/or in human intracellular fluid. Support for this is set out in the paragraph at lines 13-25 of page 7 of applicant's specification. The person of ordinary skill in the art knows what is in human extracellular fluid and in human intracellular fluid. Thus, applicant's specification clearly provides a standard to one of ordinary skill in the art for being apprised of the metes and bounds of the scope.

Accordingly, applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. §112, second paragraph, of dependent claim 15 with respect to the terms "potassium protein complexes" and "sodium protein complexes".

## Rejections under 35 U.S.C. §103:

The Examiner rejected claims 1 – 12 under 35 U.S.C. §103(a) as being unpatentable over Friedrichs (DE Utility Model No. 296 16 496, as translated from German into English, translation provided by the Examiner) in view of Taylor et al. (US Patent No. 5,869,104) and New York Daily News (July 19, 2001).

Applicant respectfully traverses.

Friedrichs teaches a cellulite <u>peeling</u> composition that is an emulsion of orange oil, milk serum [whey], sea salt (55-65%), and an emulsifying ointment (Ungentum aqueous) for use on cellulite. Such creamy ointments are discussed in the paragraph at lines 5-9 of page 4 of applicant's specification, which mentions a major drawback of a greasy-feeling residue. Besides being an ointment that can leave a greasy feel, Friedrichs has the additional drawback of the unsightliness of the peeling.

In contrast, applicant's formulation comprises a solid block, not an ointment, and also applicant's formulation is not a cellulite peeling composition. Applicant's independent claim 1 clearly states that the solid block formulation is applied by "gently gliding it over the affected skin in a manner insufficient to cause abrasion and debridement of the affected skin". There is no peeling in the present invention.

Since Friedrichs is teaching a debriding ointment for peeling the skin, the teaching is away from the present invention which specifically does not abrade nor debride.

Applicant Bass is a co-inventor of Taylor et al. (US Patent No. 5,869,104). This patent is discussed on page 9 of applicant's specification. In one embodiment of Taylor et al. '104, a solid block of NaCl is applied gently to the skin, but this composition is for topical treatment of skin conditions that are <u>infections</u>, for instance, impetigo.

That a topical composition works for skin infections does not make obvious to the person of ordinary skill in the art that the topical composition will work for cellulite. Many prior art topical treatments for skin infections are commercially available, but to the best of applicant's knowledge, none of them is also marketed for topical treatment of cellulite.

Cellulite is not an infection of the skin. As clearly explained in the paragraph at the top of page 3 of applicant's specification, cellulite is from fat (adipose tissue) and retained water, resulting in the cellulite-affected skin having a honeycomb pattern in a given area of the skin that tends to bulge.

Since Taylor et al. '104 teach topical treatment of skin conditions that are <u>infections</u>, the teaching is irrelevant to the present invention which is topical treatment of skin having a honeycomb look caused by the arrangement of adipose tissue and water, namely cellulite-affected skin.

New York Daily News teaches mechanical massage, with rollers and suckers, on pigs, for treating cellulite. In New York Daily News, there is no topically applied formulation whatsoever. Such endomologie that is a deep massage by rolling and suction to smooth the clumping of fat from cellulite is discussed in the paragraph at lines 11 - 14 of page 4 of applicant's specification.

In contrast, applicant's method is with a solid block formulation of NaCl and/or KCl, and the solid block is not applied with a deep massage by rolling and suction to smooth the clumping of fat. Applicant's independent claim 1 clearly states that the solid block is applied by "gently"

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gliding it over the affected skin in a manner insufficient to cause abrasion and debridement of the affected skin".

Since New York Daily News teaches mechanical massage, with rollers and suckers, and no formulation, the teaching is away from the present invention which specifically requires gently gliding the solid block. There is no deep massage by rolling and suction in the present invention.

Thus, what is obvious from the combination of these 3 references is to massage deeply, with rollers and suction, using a topical treatment for infections, so that the massage with the topical infection treatment causes peeling of the cellulite-affected skin. This is most certainly a teaching away from the present invention of claims 1-12 and cannot possibly render these claims obvious.

Moreover, for the following additional reasons, the combination of these 3 references does not render obvious any of dependent claims 2, 5, and 6.

Dependent claim 2 requires about 95 – 100 % NaCl and/or KCl. Friedrichs has only 55 – 65 % sea salt.

Dependent claim 5 requires that the block of NaCl and/or KCl is free of a carrier. Friedrichs has a carrier, namely emulsifying ointment (Ungentum aqueous).

Dependent claim 6 requires that the block of NaCl and/or KCl is free of other topical medicaments and cosmetics for topical treatment of cellulite. Friedrichs has orange oil and milk serum.

Accordingly, applicant respectfully requests the Examiner to withdraw the rejection of claims 1 – 12 under 35 U.S.C. §103(a) over Friedrichs, Taylor et al. '104, and New York Daily News.

Next, the Examiner rejected dependent claim 13 under 35 U.S.C. §103(a) as being unpatentable over Friedrichs, Taylor et al. '104, and New York Daily News as applied to claims 1 – 12 above, and further in view of Koike et al. (US Patent No. 6,461,623).

Dependent claim 13 is directed to an embodiment with the NaCl and KCl in a weight ratio amount of Na:K up to about 1:1. Thus, dependent claim 13 requires the presence of KCl.

The above comments, vis-à-vis Friedrichs, Taylor et al. '104, and New York Daily News in combination teaching to massage deeply, with rollers and suction, using a composition that

topically treats infections, so that the massage with the topical infection treatment causes peeling of the cellulite affected skin, are incorporated here by reference.

Furthermore, there is no KCl in either of Friedrichs or Taylor et al. '104, and certainly not in New York Daily news which is silent vis-à-vis any formulation whatsoever.

Koike '623 teaches a massage composition of zeolite (which becomes warm upon hydration), polyhydric alcohol, and copolymers of methacrylic acid. Optionally, NaCl or KCl may be added for a scrubbing effect and skin contracting effect.

As noted above, applicant's independent claim 1 clearly states that the solid block is applied by "gently gliding it over the affected skin in a manner insufficient to cause abrasion and debridement of the affected skin". There is no scrubbing in the present invention.

Since Koike et al. are teaching a debriding composition for scrubbing the skin in their optional embodiment with NaCl or KCl, the teaching is away from the present invention which specifically does not abrade nor debride.

Thus, the only teaching that adding Koike et al. '623 to Friedrichs, Taylor et al. '104, and New York Daily News would do is that the combination of the 4 references would teach to massage deeply, with rollers and suction, and also with scrubbing, using a topical treatment for infections, and also using zeolite that heats up when hydrated, so that the massage with the topical infection/zeolite heat treatment causes peeling of the cellulite affected skin. This is most certainly a teaching away from the present invention of dependent claim 13 and cannot possibly render this claim obvious.

Accordingly, applicant respectfully requests the Examiner to withdraw the rejection of dependent claim 13 under 35 U.S.C. §103(a) over Friedrichs, Taylor et al. '104, New York Daily News, and Koike et al. '623.

Last, the Examiner rejected claims 14 and 15 under 35 U.S.C. §103(a) as being unpatentable over Friedrichs (DE Utility Model No. 296 16 496, as translated from German into English) in view of Taylor et al. (US Patent No. 5,869,104) and New York Daily News (July 19, 1991) as applied to claims 1 – 12 above, and further in view of Aldrich (1996).

Claims 14 and 15 are dependent claims directed to an embodiment where the solid block of NaCl and/or KCl comprises another ingredient of the kind of naturally present in human extracellular fluid and/or in human intracellular fluid, for instance, potassium carbonate,

potassium protein complexes, potassium phosphate, sodium carbonate, sodium protein complexes, and/or sodium phosphate.

The comments above, vis-à-vis Friedrichs, Taylor et al. '104, and New York Daily News in combination teaching to massage deeply, with rollers and suction, using a composition that topically treats infections, so that the massage with the topical infection treatment causes peeling of the cellulite affected skin, are incorporated here by reference.

Furthermore, there is no human extracellular fluid nor human intracellular fluid in either of Friedrichs or Taylor et al. '104, and certainly not in New York Daily news which is silent visà-vis any formulation whatsoever.

Aldrich is a supply catalogue from this company, the catalog being for purchasing bulk quantities of materials such as NaCl and/or KCl, where the cited catalog pages specifically mention NaCl and KCl. The catalog page for NaCl notes that high purity NaCl contains trace amounts of phosphate ions, which is well known. The Aldrich catalog pages are silent about ingredients of the kind naturally present in human extracellular fluid and/or in human intracellular fluid.

The well known fact that high purity NaCl contains trace amounts of phosphate ion does not mean that the Aldrich catalog pages are teaching or even suggesting the optional addition another ingredient of the kind of naturally present in human extracellular fluid and/or in human intracellular fluid into a formulation for the topical treatment of cellulite.

As noted, it is well known that high purity NaCl contains certain impurities and is not 100% NaCl. That is not the point.

Rather, the point is that the only teaching that adding the Aldrich catalog pages to Friedrichs, Taylor et al. '104, and New York Daily News would do is that the combination of the 4 references would teach to massage deeply, with rollers and suction, using a topical treatment for infections, and so that the massage with the topical infection treatment causes peeling of the cellulite affected skin, and by the way, "high purity" NaCl contains a few impurities such as phosphate ion. This is most certainly a teaching away from the present invention of claims 14 and 15 and cannot possibly render these claims obvious.

Accordingly, applicant respectfully requests the Examiner to withdraw the rejection of claims 14 and 15 under 35 U.S.C. §103(a) over Friedrichs, Taylor et al. '104, New York Daily News, and the Aldrich catalog pages.

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### **CONCLUSION**

In view of the above amendments and remarks, applicant respectfully submits and requests the following. Applicant submits the claims are sufficiently definite, and requests the Examiner to withdraw the claim rejections under 35 U.S.C. §112, second paragraph. Applicant submits the claims distinguish over the cited references in any combination, and requests the Examiner to withdraw the claim rejections under 35 U.S.C. §103(a). Hence, applicant submits the present application is in proper condition for allowance, and requests official notification of allowance.

## **DEPOSIT ACCOUNT**

Although it is believed no fee is due, the Commissioner hereby is authorized to charge any deficiencies of payment associated with this Communication, or to credit any overpayment, to **Deposit Account No. 13-4365**.

Respectfully submitted,

Moore & Van Allen PLLC

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